

Message

From: Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]
Sent: 3/23/2020 8:38:22 PM
To: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Subject: RE: Oxitec response to comment

Okay – thanks, Elizabeth!

From: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Sent: Monday, March 23, 2020 4:30 PM
To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Subject: FW: Oxitec response to comment

Hi, Ben. Just wanted to let you know that I did not attach the whole r2c document – just the section that is responsive to your questions. Hope that works. Let me know if you need anything else.

From: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Sent: Monday, March 23, 2020 4:20 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Cc: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Subject: RE: Oxitec response to comment

Thanks, Eric.

- Ben

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Monday, March 23, 2020 3:54 PM
To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Cc: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Subject: Oxitec response to comment

Ben,

We responded to your questions in red below. We've also attached a draft r2c document and a copy of the CDC import permit supplied by Oxitec for your reference. Let me know if you want to discuss anything.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Sent: Wednesday, March 18, 2020 1:12 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Subject: RE: Oxitec response to comment

Eric,

First, although I am still aiming to get draft responses to you by Sunday (March 22), it might not be until March 31 that I can complete this task. However, it looks like I am probably not going to be on leave next week after all, but even if I am (and haven't yet finished the legal RTCs), then I'll continue working on it next week until it's done. So, I plan to get it done by March 31, regardless of whether I'm on leave next week or not. That said, please let me know ASAP if the "official" target date changes.

As to the legal comments themselves that you sent (attached for reference), here is my present thinking. Please note that I've included **bold, underlined** questions below for BPPD's response:

1) Comments Challenging EPA's Interpretation That FIFRA Can Be Used to Regulate OX5034 Mosquito

Ex. 5 Attorney Client (AC)

2) Comments Arguing the Agency Must Prepare a Full EIS Under the National Environmental Policy Act (NEPA)

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

3) Comments Stating that EPA Must Comply with the Endangered Species Act and Other Laws

Ex. 5 Attorney Client (AC)

4) Veterinary Feed Directive (21 USC 354)

Ex. 5 Attorney Client (AC)

^[1] https://www.cdc.gov/parasites/dirofilariasis/biology_d_immitis.html

^[2] Chihota, C. M., Rennie, L. F., Kitching, R. P., & Mellor, P. S. (2001). Mechanical transmission of lumpy skin disease virus by *Aedes aegypti* (Diptera: Culicidae). *Epidemiology and Infection*, **126**(2), 317–321.

^[3] Fenner, F., Day, M. F., & Woodroffe, G. M. (1952). The mechanism of the transmission of myxomatosis in the European rabbit (*Oryctolagus cuniculus*) by the mosquito *Aedes aegypti*. *The Australian Journal of Experimental Biology and Medical Science*, **30**(2), 139–152.

^[4] Kilham, L., & Dalmat, H. T. (1955). Host-Virus-Mosquito Relations of Shope Fibromas in Cottontail Rabbits. *American Journal of Epidemiology*, **61**(1), 45–54.

^[5] Mweya, C. N., Kimera, S. I., Kija, J. B., & Mboera, L. E. G. (2013). Predicting distribution of *Aedes aegypti* and *Culex pipiens* complex, potential vectors of Rift Valley fever virus in relation to disease epidemics in East Africa. *Infection Ecology & Epidemiology*, **3**(1), 21748.

^[6] Thongyuan, S., & Kittayapong, P. (2017). First evidence of dengue infection in domestic dogs living in different ecological settings in Thailand. *PLOS ONE*, **12**(8), e0180013.

Ex. 5 Attorney Client (AC)

5) Comments Questioning Whether Oxitec Can Be Released from the Contained Use Requirements of an Import Permit

Ex. 5 Attorney Client (AC)

6) EPA Should Not Rely on the Registrant Providing Assessment Data/Information

Ex. 5 Attorney Client (AC)

A) Human studies

Is there a “human studies” comment in play, here? If so, is Michelle Arling handling it? Even if Michelle is handling it, can you please send it to us in OGC, just so we’re aware of it? Michelle A sent comments. Angela Huskey looked at the text.

B) Oxitec’s purposes do not fit appropriate purposes of an EUP

Is there such a comment in play, here?
I did not see that comment in the docket.

C) Notification for export of GE insects from the EU per the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Ex. 5 Attorney Client (AC)

D) New regulations covering GE mosquitos needed in light of FDA's GFI 236

Is there such a comment in play, here?

Yes, those comments are in the piece I am sending you.

E) EPA should (must?) do a rulemaking to un-exempt biological control agents

Is there such a comment in play, here?

No. No mention of biological control agents specifically.

F) FDA vs. EPA vs. APHIS jurisdiction?

Is there such a comment in play, here?

Not really. The only comment that begins to approach this idea is in the legal section we sent to you earlier. In it the commenter argues that none of the agencies have real authority to regulate.

G) Public hearing required

Is there such a comment in play, here?

Yes. Those comments are in the piece I am sending you, draft r2c doc.

H) Migratory Bird Treaty Act and EO 13186

Is there such a comment in play, here?

No comments specifically refer to the Migratory Bird Act or EO 13186. Some comments, 0335 and 0344, state that EPA must consider all relevant laws. Those comments are in the section on EIS in the legal comments we sent you earlier.

l) "Legal" arguments regarding "no unreasonable adverse effects" finding under FIFRA

Ex. 5 Attorney Client (AC)

Please let me know if you'd like to discuss.

Thanks!

- Ben

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From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Wednesday, March 18, 2020 10:29 AM
To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Subject: RE: Oxitec response to comment

Sounds good, our meeting with Rick is at 430 so anything you can give me before that is helpful. Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Sent: Wednesday, March 18, 2020 10:28 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: RE: Oxitec response to comment

Eric,

I'll be in touch as soon as I can. Other fires burning at the moment.

- Ben

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: Wednesday, March 18, 2020 10:25 AM

To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>

Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: Oxitec response to comment

Ben,

I just wanted to check in on your progress. We have a meeting with Rick today to provide an update. As mentioned previously our stated target date in BPPD is mid-April (right now is the 15th), but the existing march 31 date has not been moved at this time.

If you don't think you will finish this week, please let me know. I know you are on leave next week, we will convey what you think is doable to Rick. If you want to discuss on the phone, I have call forwarding on and should be available after 11 am this morning.

Thanks.

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

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